DEC 1 4 2000

K002989

15. 510(k) Summary

PROCLUDE

Contact: Target Health Inc.
305 Madison Avenue, Suite 2501
New York, NY 10165

Tel: 212 681 2100
Fax: 212 681 2105

Sponsor: ORTEK THERAPEUTICS, INC.
1205 Franklin Avenue
Garden City NY 11530

Tel: 516-248-8453
Fax: 516-739-0822

15.1 Device Name

Device name: PROCLUDE

Trade Name: PROCLUDE

Common Name Prophypaste
Classification Name – Sec. 872.**6030** Oral cavity abrasive polishing agent.

15.2 Predicate Device/ Company Names and Addresses

NUPRO Prophylaxis Paste

Dentsply Preventive Care
York, PA 17404

The predicate device is listed below with its 510(k) clearance number.

PRODUCT NAME	510 (k)	CLEARANCE DATE
Nupro (Satin) Prophylaxis Paste	K912945	9/16/1991

15.3 Description of Device

Prophypaste

15.4 Intended Use

PROCLUDE is a Prophypaste to be used for cleaning and polishing procedures as part of a professionally administered prophylaxis treatment. Secondarily, PROCLUDE can be used for the management of tooth sensitivity, post-scaling and root planing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2000

Ortek Therapeutics, Incorporated
C/O Mr. Jules T. Mitchel
President
Target Health, Incorporated
305 Madison Avenue, Suite 2501
New York, New York 10165

Re: K002989
Trade Name: Proclude
Regulatory Class: I
Product Code: EJR
Dated: September 22, 2000
Received: September 25, 2000

Dear Mr. Mitchel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic

Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K002989

Device Name: PROCLUDE

Indications For Use:

PROCLUDE is a Prophypaste to be used for cleaning and polishing procedures as part of a professionally administered prophylaxis treatment. Secondarily, PROCLUDE can be used for the management of tooth sensitivity, post-scaling and root planing.

DO NOT WRITE BELOW THIS LINE

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Prescription Use X or Over-The Counter Use ___

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Susan Runyon

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002989